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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/610,960	06/30/2003	Ramin Shahidi	52755-8003.US02	4157

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EXAMINER

KHOLDEBARIN, IMAN K

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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09/06/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/610,960

Applicant(s)

SHAHIDI, RAMIN

Examiner

I Kenneth Kholdebarin

Art Unit

3737

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No: _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 03/21/05, 10/17/05, 05/19/06.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

Detailed Action

Response to Arguments

1. Applicant's arguments filed on 03/20/2006 have been fully considered but they are not persuasive. The applicant cancelled the previously pending claims and introduced new ones which had they been presented originally would have been subjected to an election restriction requirement. The newly set of claims 10-21 directed to an invention that is distinct from the invention originally claimed for the following reason(s): the current claims are drawn towards maintaining the first system using the second imaging device. The previous claims were directed to adjusting the position of a mechanical arm. Therefore the examiner found the final rejection sent out on 12/14/2005 to be a proper rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10, 14, and 18 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 10, line 4: a second image capture instrument was introduced which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention.

Claim 14, line 5, a processor-readable medium using a second image capture instrument was introduced which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention.

Claim 18, line 12, a processor operatively connected to the actuator and tracking mechanism for using a second image capture instrument was introduced which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor at the time the application was filed had possession of the claimed invention.

Appropriate correction is required.

Obviousness-Type Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 10-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of pending application, (09/792,485).

Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claimed invention is somewhat broader recitation of the application No.

09/792,485, for example, in claim 18 of present claimed invention and claim 1 of application no. 09/792,485, the Applicants claim:

"A device for maintaining a trajectory between a tip of a first tracked instrument and a target site in a patient's body, the device comprising:

(a) an articulated mechanical arm having or accommodating a distal-end first tracked instrument having a tip that has or accommodates a force contact sensor;

(b) an actuator operatively connected to the mechanical arm for adjusting the orientation of the mechanical arm, so as to maintain the trajectory between the tip of the first tracked instrument in the direction of the patient target site;

(c) a tracking mechanism for tracking the orientation of the first tracked instrument in an instrument coordinate system; and

(d) a processor operatively connected to the actuator and tracking mechanism

for: (dl) using a second image capture instrument to construct an image of the target site that is defined by reference to the image-coordinate system;

- (d2) correlating the image coordinate system with an instrument coordinate system to place the target-site coordinate in the instrument coordinate system;
- (d3) determining whether the target site has moved off the first tracked instrument's trajectory towards the target site;
- (d4) after determining that the target site has moved off the first tracked instrument's trajectory towards the target site, computing a correction to the orientation of the first tracked instrument to re-orient the first tracked instrument towards the target site; and
- (d5) using the computed correction to correct the orientation of the first tracked instrument to maintain the first tracked instrument's defined trajectory toward the target site even as the first tracked instrument is moved in space outside or inside the body. “

Where the applicant claimed on application No. 09/792,485

A device for determining the optimal point of entry of a surgical tool adapted for use by a surgeon in accessing a target site within a patient's body, comprising:

- (a) an articulated mechanical arm having or accommodating a distal-end pointer;
- (b) a tracking controller for tracking the position and orientation of the pointer with respect to a predetermined target coordinate; (c) an imaging device in communication with the tracking controller for generating an image of the target site and intervening tissue as seen from a selected point outside of the body, along a line between that point and the target point coordinate; and (d) an actuator, in communication with the tracking controller, for adjusting the position of the mechanical arm so as to orient the axis of the pointer in the direction of the target point coordinate, as the pointer is moved in space to a selected position outside the body;

wherein the user can approach the target site, or view the target site and intervening tissue, along a trajectory from the selected position to the target point coordinate.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Der Brug et al.' 127 in view of Glassman et al.'288 and Yanof et al.'904 further in view of Simon '347.

Van Der Burg et al. teach an image-guided surgery system and method for determining the optimal point of entry of a surgical tool including: a multi-segmented articulated arm (6), a tracking controller (10/11) (two CCD sensor on the imaging device (10) See Fig. 1) and image memory containing pre-operative image data (13). Instead

of using an actuator, the surgeon manually adjusts the position of the arm in the direction of the target. Van Der Brug et al. do not teach a means for maintaining constant pressure and do not specifically address a computer readable medium.

Glassman et al. teach an image-guided robotic surgery system and method including: a multi-segmented articulated arm (14), a tracking controller (28), a pre-operative CT system (52), and an actuator (54) for automatically adjusting the position of the mechanical arm in response to feedback from a CT system, the tracking system and force monitoring sensor (53). Glassman et

al. further teach software (col. 3, lines 40-57 and col. 5, lines 20-30) for automatically controlling the robotic arm. It would have been obvious to one skilled in the art at the time that the invention was made to use an automated means for positioning an articulated arm as taught by Glassman et al. in the invention as taught by Van Der Brug et al. to provide a quicker means for precisely positioning a surgical tool in response to multi-variate feedback.

It would have been obvious to one skilled in the art to use computerized software for controlling the actuator as taught by Glassman et al. in the invention as taught by Van Der Brug et al. to allow for positioning of articulated arm with a high degree of accuracy and versatility.

It would have been obvious to one skilled in the art at the time that the invention was made to maintain consistent pressure on the target using the force monitor sensor as taught by Glassman et al. so as to consistently and predictably advance the tool within specific tissue.

Simon et al. teaches trajectory of the object by use of at least one of an acoustic system, an optical system, and an electromagnetic system. Computer segment of the system further executed by the computer processor: selects a first and a second trajectory from memory; projects the first trajectory into the image data to form a first set of projected points; projects the second trajectory into the image data to form a second set of projected points; calculates a first segment connecting the first set of projected points; calculates a second segment connecting the second set of projected points; computes the angle between the first and second segments

Van Der Brug et al. in view of Glassman do not teach providing an image of the target site and intervening tissue along the alignment trajectory.

In the same field of endeavor, Yanof et al.'904 teach viewing the target site and intervening tissue, along a trajectory from a selected position to the target, allowing the surgeon to optimally

select the route or path of the surgical tool prior to making an incision, in order to allow the surgeon to choose the least detrimental path to a target region (see in particular Figures 4 and 5 and col. 7, lines 20-67 and col. 8, lines. 1-43).

It would have been obvious to one skilled in the art at the time that the invention was made to have modified Van Der Brug et al. teaching to two separated camera with two sensors (fig. 1) in view of Glassman and incorporated the teachings of Yanof et al.'904 in order to allow the surgeon the flexibility of choosing the best trajectory of insertion Of the surgical instrument to choose the least detrimental path to the target region avoiding bone and damage to sot~ tissue such as arteries and the lungs (for motivation to combine see in Yanofet al.'904, col. 8, lines 38-43).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see the notice of reference cited.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to I Kenneth Kholdebarin whose telephone number is 571-270-1347. The examiner can normally be reached on M-F 8 AM- 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Iman Kenneth Kholdebarin/

08/30/2007


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